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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,080	EFFENHAUSER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17 and 20-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17 and 20-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "V-shaped cross-section" as claimed in Claim 21 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The current specification discloses a capillary channel but does not disclose the shape of the capillary channel. Furthermore, the drawings only show a capillary channel that is rectangular in shape.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 24, 26, 27, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Yassinzadeh et al (5,700,695).

Yassinzadeh et al disclose a sample collection means and further disclose a lancing unit comprising a detection zone; a capillary structure having a lancing tip configured to cut an incision in the skin, the lancing tip defining a capillary groove for drawing the body fluid from the incision to the detection zone via capillary action, wherein the capillary groove opens longitudinally along the outside of the lancing tip to permit

collection of the body fluid along the length of the lancing tip; the lancing unit includes a holding area in which a portion of the capillary structure is arranged; the holding area has a distal end from where the lancing tip extends and a top surface; the capillary groove opens along the top surface of the holding area; the lancing unit includes a plate capping the holding area; the plate covers a portion of the capillary groove; the plate defines a window over a detection zone; the capillary structure includes a solid needle with a capillary groove defined therein; the detection zone includes an electrochemical detector for analyzing the body fluid; the lancing tip has a distal end that initially contacts the skin during lancing; and the capillary groove further opens at the distal end of the lancing tip. See Figures 2, 3 and 8; Column 4, lines 6-46 and 64-67; and Column 5, lines 1-6.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 13-17, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al (4,637,403) in view of Yassinzadeh et al (5,700,695). Garcia et al disclose a glucose monitoring system and further disclose a drive unit having a holder, wherein the holder is moved from a first position into a second position when the drive unit is activated; a disposable lancing unit which has a holding area that

is removably positioned in the holder; an elongate capillary structure, wherein the proximal end of the capillary structure comprises at least one capillary channel for transporting body fluid connected to the holding area; a distal end of the capillary structure defining a tip which is suitable for piercing skin, wherein the distal end of the capillary structure is located outside the skin when the holder is arranged in the first position and inserted into the skin up to a puncture depth in the second position; wherein the drive unit moves the lancing device such that after the lancing device reaches the second position, the lancing device is moved back into a collecting position, such that in the collecting position a section of the capillary structure located in the skin is shorter than the section of the capillary structure when the lancing device is in the second position; the holding area has a detection zone for detecting at least one analyte, the detection zone being arranged such that the detection zone can take up body fluid from the capillary structure; the drive unit moves the lancing unit in such a manner that the lancing unit remains in the second position for a time interval and subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin; and the capillary structure and holding area are integrally connected. See Column 9, lines 41-66; Column 10, lines 50-55; Column 12, lines 15-21.

Garcia et al however fail to disclose the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end; the area of the capillary structure that is open to the outside has a channel shape; and the length of the capillary structure

is in the range from 0.3-3.0 mm and the cross-section of the capillary structure is in the range of 0.03-0.8 mm.

Yassinzadeh et al, as discussed above, disclose a lancing device and further disclose the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end; the area of the capillary structure that is open to the outside has a channel shape; and the length of the capillary structure is in the range from 0.3-3.0 mm and the cross-section of the capillary structure is in the range of 0.03-0.8 mm. See Figures 2, 3 and 8; Column 4, lines 6-46 and 64-67; and Column 5, lines 1-6.

Since both Garcia et al and Yassinzadeh et al disclose lancing devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancet of Garcia et al, to include the use of an open capillary channel, as per the teachings of Yassinzadeh et al, since it would provide an alternative means of drawing blood into the holding area for testing.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the open channel of the capillary structure from the distal end to the proximal end because the Applicant has not disclosed that the open channel from the distal end to the proximal end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Yassinzadeh et al's lancing device, and the Applicant's invention to perform equally well with either the open channel as taught by Yassinzadeh et al or the claimed open channel in Claim 14 because both

open channels would perform the same function of drawing a blood sample from the sample site through the use of capillary action.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al (4,637,403) and Yassinzadeh et al (5,700,695) as applied to claim 13 above, and further in view of Mauze et al (6,375,627 B1).

Garcia et al and Yassinzadeh et al, as discussed above, disclose a lancing system but fail to disclose the holding area and the capillary structure are made from silicon.

Mauze et al disclose a lancing system and further disclose a lancing system but fail to disclose the holding area and the capillary structure are made from silicon. See Column 6, lines 54-56.

Since Garcia et al, Yassinzadeh et al, and Mauze et al disclose lancing systems, one of ordinary skill in the art at the time the invention was made to modify the combination of Garcia et al and Yassinzadeh et al, to make the lancing element of silicon, as per the teachings of Mauze et al, since it is well known in the art to utilize silicon for a lancing material.

9. Claims 25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yassinzadeh et al (5,700,695) as applied to claim 24 above, and further in view of Garcia et al (4,637,403).

Yassinzadeh et al, as discussed above, disclose a lancing element, but fail to disclose the drive unit, wherein the drive unit is coupled to the lancing element; and the detection zone includes an optical detector for analyzing the body fluid.

Garcia et al, as discussed above, disclose a glucose monitoring system and further disclose the drive unit, wherein the drive unit is coupled to the lancing element; and the detection zone includes an optical detector for analyzing the body fluid. See Column 9, lines 41-66; Column 10, lines 50-55; Column 12, lines 15-21.

Since both Yassinzadeh et al and Garcia et al disclose lancing devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancet of Yassinzadeh et al, to include the use of a drive unit and a detection zone for an optical detector, as per the teachings of Garcia et al, since it would provide a means of lancing the skin to obtain a blood sample for testing.

10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yassinzadeh et al (5,700,695) as applied to claim 24 above, and further in view of Ramel (5,540,709).

Yassinzadeh et al, as discussed above, disclose a lancing element, but fail to disclose the capillary structure includes a pair of needles joined together.

Ramel discloses a lancing device and further discloses the capillary structure includes a pair of needles joined together. See Figures 17a and 17b.

Since both Yassinzadeh et al and Ramel disclose lancing devices, it would have been obvious to one of ordinary skill in the art to modify the lancing device of Yassinzadeh et al to include the use of a capillary structure comprising a pair of needles joined together, as per the teachings of Ramel, since it would provide an alternative means of creating a capillary channel for drawing blood from the lancing site.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yassinzadeh et al (5,700,695) as applied to claim 24 above, and further in view of Eriksen (2,359,550).

Yassinzadeh et al, as discussed above, disclose a lancing element, but fail to disclose the capillary structure includes a stranded wire with the capillary groove formed between adjacent wires.

Eriksen discloses a vaccination needle and further discloses the capillary structure includes a stranded wire with the capillary groove formed between adjacent wires. See Figure 1.

Since both Yassinzadeh et al and Eriksen disclose lancing devices, it would have been obvious to one of ordinary skill in the art to modify the lancing device of Yassinzadeh et al to include the use of a capillary structure includes a stranded wire, as per the teachings of Eriksen, since it would provide an alternative means of creating a capillary channel for drawing blood from the lancing site.

Response to Arguments

12. Applicant's arguments with respect to claims 13-17 and 20-33 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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